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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,993	07/20/2001	Kazuo Kobayashi	081356/0154	4879

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EXAMINER	
STEADMAN, DAVID J	

ART UNIT	PAPER NUMBER
1652	14

DATE MAILED: 01/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/700,993	KOBAYASHI ET AL.	
	Examiner	Art Unit	
	David J. Steadman	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *1 and 9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-8 and 10-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *1 and 12* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Application Status

Claims 1-15 are pending in the application.

Applicants' election without traverse of Group II, claims 2-8 and 10-15 in Paper No. 11, filed 11/12/02, is acknowledged.

Claims 1 and 9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim.

Claims 2-8 and 10-15 are being examined on the merits.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

[1] Claims 2-4 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are drawn to genes encoding polypeptides having endo-beta-N-acetylglucoaminidase activity. The claims read on a product of nature and should be amended to indicate the hand of the inventor, e.g., by insertion of "purified" or "isolated". See MPEP § 2105. It is noted claims 5, 6, 10, and 11 have not been rejected based on the examiner's interpretation of the term "derived from". See item [2] part b. below.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

[2] Claims 3-6 and 10-15 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 3 (claims 10 and 12 dependent therefrom) and 4 (claims 11 and 13 dependent therefrom) are indefinite in the recitation of "stringent conditions" as the specification does not define what conditions constitute "stringent". What hybridization conditions are considered "stringent" varies widely in the art depending on the individual situation as well as the person making the determination. As such it is unclear how homologous to the sequence of a gene of claim 3 or 4 a sequence must be to be included within the scope of these claims. It is suggested that applicants specify the conditions that are considered to be "stringent".

b. Claims 5 (claims 6, 14, and 15 dependent therefrom), 10, and 11 are indefinite in the recitation of the term "derived from". It is unclear from the claims and the specification as to the meaning of the term and it is unclear as to applicants' intended scope of derivatives of a gene from a microorganism of the genus Mucor. For the purposes of examination, the examiner has interpreted the term to mean "isolated from" and the claims have been examined accordingly.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

[3] Claims 2-8 and 10-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 2 part (b) (claims 5-8, 14, and 15 dependent therefrom) is directed to an endo-beta-N-acetylglucosaminidase gene encoding a protein having an amino acid sequence of SEQ ID NO:3 with any deletion, substitution, insertion, or addition of at least one amino acid and having endo-beta-N-acetylglucosaminidase activity. Claim 3 part (d) (claims 10 and 12 dependent therefrom) is drawn to a gene comprising a DNA that hybridizes under stringent conditions with SEQ ID NO:2 encoding a protein having endo-beta-N-acetylglucosaminidase activity. Claim 4 (claims 11 and 13 dependent therefrom) is drawn to a gene that hybridizes under stringent conditions with the gene of claim 2 and comprises a DNA encoding a protein having endo-beta-N-acetylglucosaminidase activity. The claims are rejected because they are drawn to a genus of genes that have not been adequately described in the specification. The specification teaches the structure of only a single representative species of such genes, i.e., SEQ ID NO:2 encoding the endo-beta-N-acetylglucosaminidase of SEQ ID NO:3. Moreover, the specification fails to describe any other representative species by any relevant, identifying characteristics or properties other than the functionality of being a gene encoding an endo-beta-N-acetylglucosaminidase or being a gene that hybridizes under unspecified conditions to a gene encoding an endo-beta-N-acetylglucosaminidase. This recitation fails to provide a sufficient description of the claimed genus of proteins as it merely describes the functional features of the genus without providing any definition of the structural features of the species within the genus. The CAFC in *UC California v. Eli Lilly*, (43 USPQ2d 1398) stated that:

> "In claims to genetic material, however a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA", without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus".

Similarly with the claimed genus of genes, the functional definition of the genus does not provide any structural information commonly possessed by members of the genus that distinguish the species within the genus from other genes such that one can visualize or recognize the identity of the members of the genus. Given this lack of description of representative species encompassed by the genus of the claim,

the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

[4] Claims 2-8 and 10-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the nucleic acid of SEQ ID NO:2 encoding the endo-beta-N-acetylglucosaminidase of SEQ ID NO:3, does not reasonably provide enablement for *any* endo-beta-N-acetylglucosaminidase gene encoding a protein having an amino acid sequence of SEQ ID NO:3 with any deletion, substitution, insertion, or addition of at least one amino acid and having endo-beta-N-acetylglucosaminidase activity (claim 2 part (b)), *any* gene comprising a DNA that hybridizes under stringent conditions with SEQ ID NO:2 encoding a protein having endo-beta-N-acetylglucosaminidase activity (claim 3 part (d)), or *any* gene that hybridizes under stringent conditions with the gene of claim 2 and comprises a DNA encoding a protein having endo-beta-N-acetylglucosaminidase activity (claim 4). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Undue experimentation would be required for a skilled artisan to make the entire scope of claimed genes. Factors to be considered in determining whether undue experimentation is required, are summarized in *In re* Wands (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 2 part (b) (claims 5-8, 14, and 15 dependent therefrom), 3 part (d) (claims 10 and 12 dependent therefrom), and 4 (claims 11 and 13 dependent therefrom) are so broad as to encompass *any* gene as describe above. The scope of the claimed genes is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of genes broadly encompassed by the claims. Since the nucleotide sequence of an encoding nucleic acid determines the encoded protein's structural and functional properties, predictability of which changes can be tolerated in a protein's amino

acid sequence and obtain the desired endo-beta-N-acetylglucosaminidase activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. The examiner can find no disclosure of such guidance in the specification or the prior art. In this case the enablement provided by the disclosure is limited to the nucleic acid of SEQ ID NO:2. While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within an encoding nucleic acid where modifications can be made with a reasonable expectation of success in obtaining an encoded protein with the desired endo-beta-N-acetylglucosaminidase activity are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass *any* gene as described above because the specification does not establish: (A) regions of the protein structure which may be modified without affecting endo-beta-N-acetylglucosaminidase activity; (B) the general tolerance of the endo-beta-N-acetylglucosaminidase of SEQ ID NO:3 to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any residues of the endo-beta-N-acetylglucosaminidase of SEQ ID NO:3 with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices for amino acid substitution is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly *any* gene as described above. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re* Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation

left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re* Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

[5] Claims 2, 7, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Takegawa et al. (EP 0769550; IDS reference cited in Paper No. 12; hereafter referred to as "Takegawa"). Claim 2 (in pertinent part) is drawn to an endo-beta-N-acetylglucosaminidase gene encoding a protein having an amino acid sequence of SEQ ID NO:3 with deletion, substitution, insertion, or addition of at least one amino acid and having endo-beta-N-acetylglucosaminidase activity. Claim 7 is drawn to a recombinant vector comprising the gene of claim 2 and claim 8 is drawn a transformant comprising the vector of claim 7. In accordance with MPEP 2111, which directs the examiner to give a claim its broadest reasonable interpretation, claim 2 part (b) has been interpreted as meaning any gene that encodes a polypeptide having endo-beta-N-acetylglucosaminidase activity. Takegawa teaches the nucleotide sequence (SEQ ID NO:2, pages 13-15) of a gene encoding an *Arthrobacter protoformiae* endo-beta-N-acetylglucosaminidase (SEQ ID NO:1, pages 15-17). Takegawa teaches insertion of this gene into an expression vector and transformation of *E. coli* with the resulting plasmid (page 11). This anticipates claims 2, 7, and 8 as written.

Conclusion

[6] All claims are rejected. No claim is in condition for allowance.

[7] Claims 3-6 and 10-15 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 101 and/or 112, first and/or second paragraphs, set forth in this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Thursday from 6:30 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for this Group is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

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